

# Exhibit M

Altman (2006)	264	29-50	-	X	-	-	Yes <sup>1</sup>	OAB-4
Zhang (2006)	4684	20+	-	X	-	-	Yes <sup>2</sup>	UUI-1
Moller (2000)	1247	40-60	-	X	-	-	No	UUI-1
Parazzini (2003)	2205	40+	X	-	-	-	No	UUI-2
Rortveit (2003)	15,307	20-65	X	-	-	-	No	UUI-2
Foldspang (1992)	2,631	30-59	X	-	-	-	No	UUI-2
1. Associated with vaginal births								
2. Associated with all births (c-sections not excluded)								

**Table 2. Results of logistic regression for estimating odds ratio for meeting OAB and Urge Incontinence Criteria<sup>1</sup>**

Case Definition	UUI	SUI	Urgency	Frequency	Nocturia	Number of Cases	Adjusted OR (95%CI) for 1+ births (vs. 0)
OAB-1	No	No	Yes	Yes / no	Yes / no	255	1.29 (0.86-1.95)
OAB-2	No	No	Yes	Yes	Yes / no	104	1.22 (0.68-2.19)
OAB-3	No	No	Yes	Yes	Yes	134	1.05 (0.64-1.74)
OAB-4	Yes / no	Yes / no	Yes	Yes / no	Yes / no	949	<b>1.88 (1.40-2.52)</b>
UUI-1	Yes	Yes / no	Yes / no	Yes / no	Yes / no	655	<b>1.87 (1.34-2.60)</b>
UUI-2	Yes	No	Yes / no	Yes / no	Yes / no	149	1.20 (0.71-2.01)
1. Adjusted for age, BMI, diabetes, and birth history (0/1+)							

**Presentation Number:** 103

**Consent obtained from patients:** Yes

**Level of support:** Not Applicable

**Work supported by industry:** No

#### **VAGINAL MESH SHRINKING - ULTRASOUND ASSESSMENT AND QUANTIFICATION**

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#### **Objective:**

Polypropylen meshes are frequently used in vaginal reconstructive surgery. Its usage is limited by lack of good quality studies together with general awareness of mesh associated

complication like protrusion and shrinking. Can we clinically visualize and objectively assess the mesh and its shortening after implantation?

**Background:**

We know from experimental studies that the large mesh area caused strong inflammatory reaction which results in integration of the mesh to the tissue and is associated with retraction- shrinking of the mesh. This effect is observed during postoperative clinical examination as stiffness of the vaginal wall. This effect is a part of ongoing discussion about the appropriate size of the mesh - are the meshes too small or too large? The shrinking of the polypropylene mesh is described from 30% up to 50% in some animal studies. There are lacking clinical data. There are two mechanisms causing shortening of mesh - folding caused by insufficient spread of the mesh and tissue retraction - shrinking. There are enough studies describing ultrasound assessment of the tapes and the mesh is visualized in the same manner. We assessed the effect of implanted mesh after anterior vaginal repair.

**Methods:**

The assessment consisted of 3D/4D ultrasound of the anterior vaginal wall thickness including the urinary bladder wall using a GE Voluson 730 Expert or GE E8 system in patient with symptomatic anterior vaginal wall prolapse POPQ grade  $\geq$ II included in randomized interventional study, comparing traditional anterior repair (group - AR; n=12), anterior repair with free insertion of self-cut mesh(Gynemesh) (Group - Mesh; n=17) or with a large - Prolift mesh,(Group - Prolift; n=18 ). The measurements were taken in region between 15 to 20 mm from urethro-vesical junction in mid-sagittal plane. Before the surgery we measured the bladder wall thickness, and the entire vaginal wall including the bladder wall. Subtraction of the bladder wall thickness from entire anterior vaginal wall we calculate the thickness of vaginal mucosa with underlying fascia (vaginal wall). During the surgery we measured the length of the mesh (Original length). Fourth day after surgery we performed early ultrasound examination and measured the mesh length (Early US length) in mid-sagittal plane. The late ultrasound examination was performed 3 - 5 month after surgery to measure the anterior vaginal wall thickness and again the mesh length. (Late US length) All measurements were taken 3 times and we used the mean value. Mesh shortening in percent was calculate as a proportion of the different length measurements see table 2

**Results:**

We analysed first 47 patients randomised in three groups, mean age 59.4 SD 9.6; mean BMI 27.3 SD 3.6; parity 2.2, with no differences between groups. In group AR there is no change in vaginal wall thickness before and after surgery (+0.7mm p-value 0.335 -NS). In groups with meshes there is increase in vaginal wall thickness by 1.3 mm (p-value 0.0001). Results for mesh shortening are included in Tables 1,2.

Table 1	Group Prolift					Group Mesh				
( mm )	N	mean	SD	median	QR	N	mean	SD	Median	QR
Original length	17	85.5	16.1	90	0.0	18	44.8	5.3	44.0	2.5
Early US length	17	53.4	11.3	56	17.8	18	40.4	1.9	40.8	2.0
Late US length	17	49.8	9.0	49	10.3	18	31.8	4.7	32.4	5.1

Table 2 Mesh Shortening in %						
		Group Prolift	Group Mesh	Group Prolift	Group Mesh	K p-value
		N	N	median	median	

Late US length /Original length		17	18	45%	25%	0.001
Late US length /Early US length	Shrinking	17	18	16%	20%	0.4180
Early US length/Original length	Folding	17	18	36%	7%	0.0009

**Conclusions:**

We quantified with ultrasound imaging shrinking of the mesh and we could differentiate mesh shrinking from folding caused by the surgery. The Gynemesh shrinks one fifths of its length. The folding has a major impact on the final length of the large meshes (36%) and it seems to be irreversible as we see in table 2. It might raise the question about the appropriate size of the mesh. The significant increase in vaginal wall thickness after vaginal surgery is apparently caused by the mesh and not by the surgery.

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# **POSTOPERATIVE URINARY BLADDER CATHETERISATION AFTER ANTERIOR COLPORRHAPHY**

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**Objective:** To determine whether catheterization for 2 days leads to significantly more patients with urinary bladder retention compared to our standard length of catheterization for 5 days after an anterior colporrhaphy. Secondary outcome measures are urinary tract infections and hospital stay.

**Background:**

Two studies have been performed regarding the appropriate length of postoperative catheterization after an anterior colporrhaphy. One randomized controlled trial in 100 patients has compared short term and long term catheterization after anterior colporrhaphy. This study showed 40% of patients needing recatheterisation after removing the catheter on the first postoperative day versus 9% of patients with retention after removing the catheter on the fifth postoperative day.[1] Another study in 50 patients after anterior repair showed no difference in occurrence of retention after removing the catheter on the first and on the third day (8%).[2] When bladder function has not been restored in almost half of patients we do think that removing the catheter on the first postoperative day is too soon. Literature is showing 40% recatheterisation after removing the catheter on the first day postoperatively, 8% recatheterisation on the third day en 9% on the fifth day, probably the turning point is on the second day.

**Methods:**

In three hospitals a multicenter randomized controlled trial was conducted to compare catheterization for 2 and 5 days postoperatively after anterior colporrhaphy. Digital randomization was performed in blocks of 6 patients. Residual volumes were measured by bladder (ultrasound) scan, 6-8 hours after removing the catheter. A residual volume after